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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,391	02/05/2007	Michael Huempel	7003/52	9038
7590	10/19/2007		EXAMINER DENTZ, BERNARD I	
Mayer & Williams 251 North Avenue West 2nd Floor Westfield, NJ 07090			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 10/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/575,391	HUEMPEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bernard Dentz	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07 April 2006 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2,3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyamoto et al, *Planta Medica* vol.64, p.516, (1997). It discloses that 8-isopentenylnaringenin significantly suppressed the increase in bone resorption associated with ovariectomy and it is strongly suggested that it like estrogen can be used in preventing bone loss in postmenopausal women. See p. 516.

Claims 2,3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitaoko et al , *Planta Medica*, vol.64, p.511 (1997). It is an article, from the same group as above, which discloses the preparative part of the work. It discloses a method for the isolation of 8-isopentenylnaringenin from the heartwood of *Anazagorea luzonenensis*, a tree native to Thailand, extracts of which have been used in Thai medicine( see p.513). It also discloses that 8-isopentenylnaringenin fact may be used to treat hormone dependent osteoporosis.

It further makes the above in racemic form from commercially available naringenin and compares the estrogenic activity with each of the optical isomers which were prepared by chromatography from the natural product. They were unable to show a significant difference in the dose dependent effects of the respective enantiomers

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along with the synthetic racemate on the inhibition of [<sup>3</sup>H]-estradiol to the estrogen receptor. See p. 514, col. 1, last paragraph to p. 514, col. 2, first paragraph.

See p. 515, col. 1 first paragraph for the statement that "Compound 1 was found to possess estrogen uterotrophic effectiveness and also to prevent bone loss caused by ovariectomy".

Claim 2 recites in its entirety "8-Prenylnaringenin preparation prepared by the method according to claim 1". It is well known that product-by-process claims are normally construed as reading on the product. In this case the product is taught by the above references and thus the claim is anticipated.

Further there is no indication in claim 1 in which the product steps are recited, as to how and if the preparation is separated from the completed reaction mixture from step d.

The 8-prenylnaringenin of both of these references and is over 95% pure and of course would have the same pharmacological properties recited in claim 5.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto et supra or Kitaoka et al, supra. It would be obvious to use 8-prenylnaringenin or

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compositions consisting essentially or primarily of same for the production of a medicament for the prevention and treatment of hormone dependent osteoporosis simply because the references teach that the various forms of the compound are effective for the above.

Claim 1 and 2 rejected under 35 U.S.C. 102(b) as being anticipated by Gester et al. It discloses the synthetic method for making of 8-prenylnaringenin recited in instant claim. Instant claim 1 does not recite how the product is isolated. It reads on doing nothing to the completed reaction mixture in which the compound is produced. At this point before the reference uses chromatography to isolate the above compound the steps are exactly the same and thus the completed reaction mixture containing the compound is the same. Claim 2 reads on that completed reaction mixture and thus is also deemed anticipated.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gester et al. Applicants' method of purifying the final product involves repeated washing, dissolving followed by filtration These are old standard methods. Thus use of these methods rather than flash chromatography taught by the reference at p. 1018, par. 3.3 represents a modification obvious to one of ordinary skill in the art.

These steps are not recited in the claims. They are taken from the Examples in the specification. The rejection is made to improve prosecution.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dentz

10-17-2007



BERNARD DENTZ  
PRIMARY EXAMINER